



PATENT
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Attorney Docket No. 06530.0276-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)
Marc O. SCHURR et al.) Group Art Unit: 3773
Application No.: 09/957,451) Examiner: Darwin P. Erezo
Filed: September 21, 2001) Confirmation No.: 2507
For: METHODS AND DEVICES FOR)
FOLDING AND SECURING)
TISSUE)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF

Pursuant to 37 C.F.R. § 41.41, Appellant presents this Reply to the Examiner's Answer mailed October 14, 2009.

I. ARGUMENT

In addition to the arguments for reversal of the outstanding final rejection provided in Appellant's Appeal Brief filed on June 29, 2009, Appellant provides the following remarks regarding the Examiner's Answer mailed October 14, 2009.

A. The Section 103 rejection based on *Le Roy* in view of *Yoon* should be reversed.

1. **Independent Claims 1, 120, 135, and 148 and their dependents**
 - a. **Modifying the clip of *Le Roy* to be comprised of bioabsorbable material capable of disintegrating in a body is improper**

Regarding the claimed feature of being “comprised of a bioabsorbable material . . . capable of disintegrating in the body,” the Examiner notes that col. 2, ll. 34-37, of *Le Roy* states that “[u]pon release of force from the applicator the slit edges are then applied to the two sides of wound flap 16 or other *tissue* to prevent the flow of blood from severed arteries, capillaries or the like.” (Examiner’s Answer, p. 9, ll. 7-10; emphasis added by the Examiner). The Examiner contends that this disclosure of *Le Roy* “clearly shows that the clip is not limited for use with the patient’s skin.” (Examiner’s Answer, p. 9, ll. 10-11).

Although *Le Roy* states that the clip may be applied to “other tissue,” this does not necessarily mean that the “other tissue” referred to by *Le Roy* includes internal tissue. “Other tissue” simply distinguishes from two sides of a wound flap. The text cited by the Examiner does not alter that. *Le Roy* does not disclose or suggest that the clip is used internally. As noted in pp. 23-25 of the Appeal Brief, *Le Roy*’s clip is designed with the projections 18 that allow the clip to be easily and rapidly removed by hand or with the applicator tool 14. (*Le Roy*, col. 2, ll. 64-69). Since the clip 10 of *Le Roy* is intended to be removable and used externally, there is no motivation to modify the clip 10 of *Le Roy* to be made of bioabsorbable material capable of disintegrating in a body.

2. Claims 129, 142, 174, and 178

a. Le Roy and Yoon do not disclose or suggest the claimed pin, bolt, suture, staple, or rod, or the claimed barb

Regarding the claimed features of “an additional anchoring portion including one of a pin, bolt, suture, staple, and rod configured to pierce the tissue fold” and “the anchoring portion includ[ing] at least a portion in the shape of a barb configured to penetrate a surface of the fold of tissue,” the Examiner states that “the tapered tip portion of 34 of Le Roy is fully capable of piercing tissue when enough force is applied to the clip.” (Examiner’s Answer, p. 9, l. 22 to p. 10, l. 1; p. 11, ll. 2-3). Applicant disagrees that any round or blunt surface necessarily can penetrate skin, especially under normal, reasonable circumstances. This is particularly the case here where the reference specifically teaches against tissue damage. As the M.P.E.P. instructs, a reference must be considered in its entirety, including disclosures that teach away from the claimed invention. M.P.E.P § 2142.02. As noted on pp. 26 and 29 of the Appeal Brief, *Le Roy* states that the leg sections 24 “terminate in flanges 28 . . . [with] parallel undulations 30,” as shown in Figs. 4 and 5, “with blunt or rounded ends 34.” (*Le Roy*, col. 2, ll. 50-60). *Le Roy* specifically teaches away from piercing the tissue fold since the blunt or rounded ends “minimiz[e] any pain [to the wound flap] or undue damage to the tissue” so that the clip “can then be merely slipped off the wound flap 16 without noticeable damage to the tissue.” (*Le Roy*, col. 2, ll. 60-69).

3. Claims 130, 143, and 153

a. *Le Roy and Yoon do not disclose or suggest the claimed tapering portion curving away from the gap*

Regarding the claimed feature of “the distal end of one of the first and second arms includes a tapering portion curving away from the gap,” a nonlimiting exemplary embodiment of this feature is shown as a crook 306 described in paragraph [75] of Appellant’s specification and shown in Fig. 6A provided below.

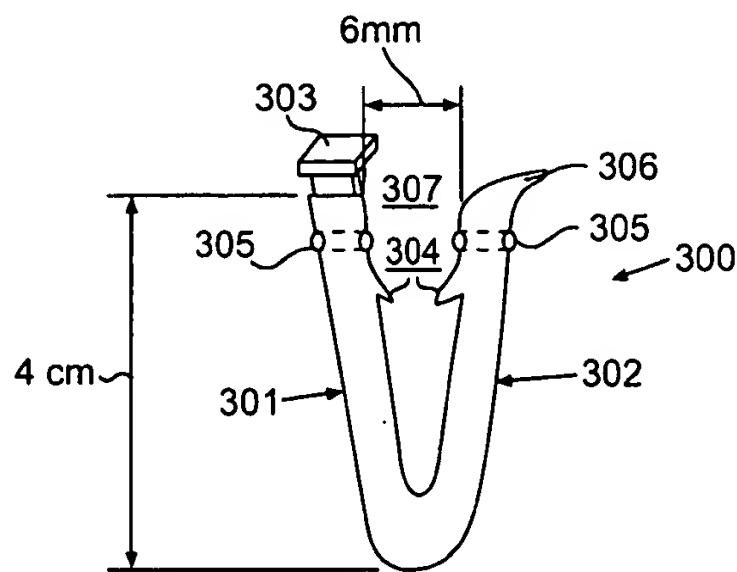
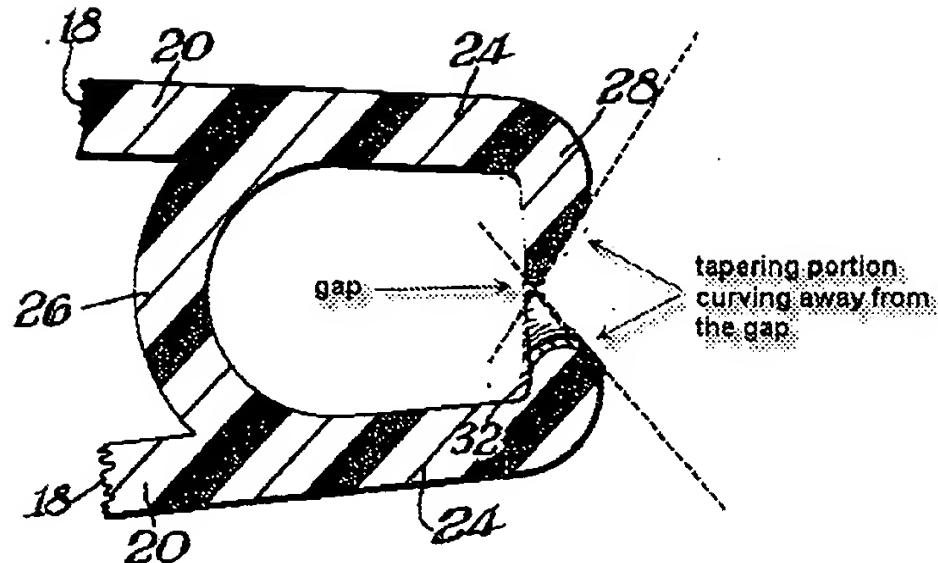


FIG. 6A

Fig. 6A shows a distal end of an arm (e.g., arm 302) that includes a tapering portion (e.g., crook 306) that curves away from a gap (e.g., opening 307).

The Examiner contends that the flanges 28 of *Le Roy* form the claimed “tapering portion curving away from the gap.” The Examiner provided the following marked-up illustration of *Le Roy*’s clip to support his argument:



(Examiner's Answer, p. 10). The Examiner asserts that each end of the flange 28 "tapers away from the gap." (Id.) However, even if one were to assume that the flanges 28 of *Le Roy* correspond to the claimed tapering portion, which Applicant does not concede, the flanges 28 do not curve or taper away from the gap indicated by the Examiner. Rather, as noted on pp. 27-28 of the Appeal Brief, the flanges 28 curve into or towards the gap, as shown by the fact that the curves or bends in the flanges 28 bring the ends of the flanges 28 close together. Accordingly, Applicant disagrees with the Examiner's description of *Le Roy*'s clip.

B. The Section 103 rejection based on *Le Roy* in view of *Yoon* and *Beaty* should be reversed.

1. Claims 132, 145, 155, 173, 175, 177, and 179

Regarding the claimed features of "[a] gripping tab . . . located at the distal end of one of the first and second arms" and a second end or distal end "of one of the first and second arms [having] a crook for providing a surface to push against to bring the arms closer together during insertion," the Examiner appears to contend that the projections 18 on *Le Roy*'s clip are gripping tabs or crooks. (Examiner's Answer, p. 11, I. 9). The Examiner also contends that the reversely turned tips 14, 16 of *Beaty* are

gripping tabs or crooks on distal ends of arms 6, 8, and that “a simple substitution of the gripping tab of *Le Roy* for the gripping tabs of *Beaty* will yield predictable results.” (Examiner’s Answer, p. 11, ll. 12-17, citation omitted). Appellant disagrees with the Examiner’s rejection because one of ordinary skill in the art would not make the proposed substitution for at least the following reasons.

a. *Modifying Le Roy to remove the projections of Le Roy at the proximal end is improper*

As noted in pp. 30-33 of the Appeal Brief, *Le Roy* states that “[w]hen force is applied to the projections [18] they act as levers to spread the longitudinal slit and facilitate the insertion of the wound flap therein.” (*Le Roy*, col. 1, ll. 38-40). *Le Roy* also states that the clip 10 “can be easily and rapidly removed either with applicator 14 or by hand” and that the projections 18 can be squeezed together and act as levers to spread the flanges 28 away from each other, thereby allowing for manual removal of the clip 10. (*Le Roy*, col. 2, ll. 64-67; Fig. 1). Therefore, the intended purpose of *Le Roy*, and a primary focus of its invention, is to include the projections 18 at the proximal end and to allow the projections 18 to be squeezed together so that they act as levers that spread the flanges 28 apart.

One of ordinary skill in the art would not modify the clip of *Le Roy*, as proposed by the Examiner, to remove *Le Roy*’s projections 18 at the proximal end. It has long been held that a proposed modification of the prior art cannot render the prior art “unsatisfactory for its intended purpose” or “change its principle of operation.” M.P.E.P. § 2143.01(V)-(VI). Modifying the clip 10 of *Le Roy* to remove the projections 18 at the proximal ends of the leg sections 24 would render the clip of *Le Roy* unsatisfactory for

its intended purpose and would change its principle of operation. If the projections 18 of *Le Roy* are removed from the proximal ends of the leg sections 24, then the projections 18 cannot be squeezed together as levers to spread the flanges of the clip apart.

b. Modifying *Le Roy* based on *Beaty* is improper

In addition, as noted in pp. 33-34 of the Appeal Brief, the Examiner's proposed modification to remove the projections 18 at the proximal end of *Le Roy*'s clip and to substitute *Beaty*'s reversely turned tips 14, 16 at the distal ends is improper. As described below, such a substitution would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation.

As noted above, the intended purpose of *Le Roy*, and a primary focus of its invention, is to include the projections 18 at the proximal end and to allow the projections 18 to be squeezed together so that they act as levers that spread the flanges 28 apart. However, modifying the clip 10 of *Le Roy* to substitute the reversely turned tips 14, 16 located on the distal ends of the arms of *Beaty* for the proximally-located projections 18 of *Le Roy* would render the clip of *Le Roy* unsatisfactory for its intended purpose and would change its principle of operation. The tips 14, 16 of *Beaty* at the distal ends cannot be squeezed together as levers to spread the flanges of the clip apart. Instead, since the tips 14, 16 are located at the distal ends of the arms, the tips 14, 16 would close the clip if squeezed together.

Also, the applicator 14 shown in Fig. 1 of *Le Roy* is only capable of squeezing together two parts, e.g., the projections 18 of *Le Roy* or the tips 14, 16 of *Beaty*. If the clip were modified as proposed by the Examiner, the applicator 14 would merely

squeeze the tips 14, 16 of *Beaty* together. If the tips 14, 16 of *Beaty* at the distal ends are squeezed together, the flanges of the clip would be forced toward each other to close the clip. Therefore, the applicator 14 of *Le Roy* would be incapable of opening the modified clip using the tips 14, 16 of *Beaty*. Since the projections 18 and the applicator 14 of *Le Roy* are intended to be used to open the clip, the proposed substitution renders the clip and the applicator 14 unsatisfactory for their intended purposes and changes their principle of operation.

II. **CONCLUSION**

For the reasons given above, and the reasons provided in Appellant's Appeal Brief, Appellant respectfully submits that the rejections of the pending claims is in error and should be reversed.

To expedite prosecution, Appellant is open to discuss the foregoing with the Examiner at any time. Appellant thus invites the Examiner to call the undersigned at the Examiner's convenience to discuss the application.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Reply Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: December 14, 2009

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